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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,750	02/19/2004	Peter M. Allred	7678.830	7378

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EXAMINER	
ROBERTS, LEZAH	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/783,750	ALLRED ET AL.	
	Examiner	Art Unit	
	Lezah W. Roberts	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *10 and 35-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 11-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *A-E*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election of Species

This application contains claims directed to the following patentably distinct species:

dental bleaching device: a dental tray and strip or patch; and

a barrier layer material.

The species are independent or distinct because a dental tray has different dimensions than a strip or patch and has a more diverse use. In the case of a barrier layer material, one material may not be used to make both a tray and strip because of their properties, such as flexibility, etc. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

During a telephone conversation with John M. Guynn on March 4, 2006 a provisional election was made with traverse to elect the species of a dental tray and polyolefin, claims 1-9 and 11-34. Affirmation of this election must be made by applicant in replying to this Office action. Claims 10 and 35-40 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim makes reference to a "tray-like" configuration. It is

not clear as to what applicant considers "tray-like". The addition of "like" makes the claim indefinite, because it is appended to a term that is otherwise definite, therefore modifying its function is unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) Claims 1-2, 11-12, 15, 18-19, 21 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Wolf (WO 99/62472).

Wolf teaches an oral strip comprising a composition for the whitening of teeth. The strips may come in several forms; one having a rectangular shape and one having notches to resemble the gum line. The strip comprises a backing layer, which is a flexible material that allows the whitening strip to conform to the arrangement of a row of teeth (page 4, lines 4-8). The backing layer may be made from a natural or synthetic polymer. The whitening agent used in the whitening composition placed on the strip includes peroxides (page 3, lines 10-12). The whitening agent is dispersed on the adhesive to form a carrier layer, which is also called the active layer (page 4, lines 9-13). The adhesives used include acrylics, copolymers, methylacrylate copolymers, acrylic acid, polyacrylates, polysaccharides, and cellulose derivatives, which are some of the compounds listed in claims 15 and 19. The strips may also comprise an inactive

layer that does not include the whitening agent (page 5, lines 2-11), which encompasses claims 21. This area will contact the gums and the back of the teeth. The inactive area comprises an adhesive in order for the area to adhere to the gums. Figure 5 shows how the inactive section adheres to the gum line, which encompasses claims 11-12. The strip may be of any length dependent on how many teeth one wants to treat (page 4, lines 23-27). The strip is applied to the teeth and takes on the general shape of the teeth. The duration of application will depend upon the type and concentration of the whitening agent (page 4, lines 27-29), which encompasses claim 27. The reference anticipates the claims insofar as it teaches a dental bleaching device comprising a whitening composition, a barrier layer and a protective adhesive comprising at least one tissue adhesive agent that includes one hydrophilic polymer.

2) Claims 1-3, 11-13, 15, 17-19, 21-23 and 26-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Wiesel (US 6,343,932).

Wiesel teaches a delivery system for whitening teeth. The system comprises a backing layer, a core and a whitening gel. The backing layer is utilized to help mold the delivery system into place. The backing layer is flexible and may be made out of, e.g., paper, foam, polyolefin or polypropylene, preferably polyolefin (col. 4, lines 62-67), as recited in claim 3. The core overlies the gums and protects them from the whitening gel. If the backing layer is removed, the core can also protect other portions of the mouth from the whitening gel, which encompasses 11-12. It also provides some structural support but is also somewhat viscous and tacky. The core may be made from

cellulose and carbopol (acrylic polymer) that is freeze-dried and does not contain whitening agent (col. 4, lines 9-22), this encompasses claims 17-19 and 21-22. It can be concluded when the freeze-dried core is moistened it becomes more adhesive to the tissue because it protects the gums from the whitening gel. The gel is preferably comprised of a 0.5% carbopol (acrylic polymer) and is activated and constitutes a whitening agent with the addition 35% hydrogen peroxide, which encompasses claims 13, 15 and 22. The whitening gel may be prepackaged with the core or come in a separate tube and added to the core before use, which encompasses claim 26. The invention is applied by molding it onto a person's teeth and can remain for any period of time (col. 5, lines 9-43), which encompasses claim 27. The reference anticipates the claims insofar as it teaches a dental bleaching device comprising a whitening composition, a barrier layer and a protective adhesive comprising at least one tissue adhesive agent that includes one hydrophilic polymer.

3) Claims 1-3, 6-9, 11-14, 16-18 and 20-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Fontenot et al. (US 5,863,202).

Fontenot et al. teach delivery devices for dental treatments. In one embodiment of the reference, the device comprises a prefabricated dental appliance composed of a non-porous polymeric material having a trough for immersing the teeth, a pre-measured amount of bleaching or other dental agent, and a buffer region (col. 6, lines 9-18). The dental appliance disclosed is U-shaped and the trough also is U-shaped as depicted by the figures. The device is made of flexible material that may be adapted to fit various

sized dental arches. This encompasses claims 2 and 6-8. The non-porous polymeric material includes urethanes that may be combined with rubbers and ethyl vinyl acetate (col. 5, lines 1-4), as recited in claim 3. The dental bleaching agent includes carbamide peroxide. The amount a bleaching agent ranges from about 5% to 20% (col. 7, lines 1-14), which encompasses claim 22. A poloxamer is used to coat the teeth with the whitening solution (col. 5, line 26). It may be concluded the poloxamer is an adhesive therefore this encompasses claims 13 and 30. The buffer region is to provide protection to the periodontal tissue from the active bleaching agent and includes an adhesive and does not have bleaching agent, which encompasses claims 21-22. Because the buffer has an adhesive it can be concluded the composition is sticky and viscous as well as hydrophilic or it would not be able to adhere to the gingival tissue, which encompasses claims 17 and 31. It may also be concluded the device overlaps the gingival margin and terminates near the margin because the buffer protects the gums as well as may provide dental agents to the gums, which encompasses claims 11-12. Other dental agents may be applied with the bleaching agent such as antioxidants, healing agents and anti-caries such as fluoride, which is a remineralizing agent as recited in claims 16 and 20. The composition and configuration of packaging for the dental appliance may vary. The packaging is preferably composed of a rigid material, such as polypropylene, polybutylene or similar material, which is molded into a cavity or cavities adapted to the dental appliance so as to maintain its intended configuration when being applied to a patient's dental arches. It may be concluded that this acts as an exoskeleton to the dental appliance and encompasses claims 23-25 and 29. It may also be concluded the

device needs the support to maintain its tray-like configuration as recited in claim 9. The packaging also contains a desiccant to keep the device free from moisture, therefore it may be concluded the gel and buffer are anhydrous, which encompasses claims 14, 18 and 33. The appliance is removed from the packaging and delivered to the teeth. Delivery of the dental agent is affected by positioning the dental appliance intra-orally with the trough aligned in a parallel fashion to the edges of the teeth. In order to correctly place the dental appliance over the teeth, the trough is pushed in the direction of the gingiva and soft tissue, also referred to herein as periodontal tissue, surrounding the dental arch toward and then around the edges of the teeth (col. 8, lines 20-35). This reads on claim 9 where the appliance must be held in the proper configuration in order to deliver the agent to the teeth. A method of treatment of dental arches and surrounding tissue includes the steps of selecting a prefabricated dental appliance composed of a non-porous polymeric material adaptable to fit a range of variously sized dental arches having a trough for immersing the teeth and periodontal tissue of the dental arch which contains a dental agent, and applying the dental appliance so as to immerse a user's dental arches in the dental agent, which encompasses claims 27. Although it does not particularly say a period time, any time the tray is on the teeth is a period of time. The kit of the reference comprises multiple trays sealed in packages as seen in the figures, which encompasses claims 23 and 26. The reference anticipates the claims insofar as it teaches a dental bleaching device comprising a whitening composition, a barrier layer and a buffer region comprising a protective adhesive.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 11-15, 17-19, 21-22 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sagel et al. (US 6,096,328) in view of Jensen et al. (US 6,086,370).

Sagel et al. teach a dental delivery system comprising a strip and an oral active agent. The dental strip may be made of polyethylene, which also encompasses polyolefin. The strip has a thickness generally less than 1 mm, which encompasses claims 4-5. The strip may be placed over the teeth or placed to overlap the gums and the teeth (see Figure 8). The oral care agents include whitening agents such as hydrogen peroxide and carbamide peroxide. The agents make up form 0.01 to 40% or

the oral care substance. The oral care substance is preferably in the form of a gel. Gelling agents are swellable polymers and include carboxypolymethylene, carboxymethyl cellulose, carboxypropyl cellulose, polyoxamers, carrageenan, Veegum, carboxyvinyl polymers, and natural gums such as gum karaya, xanthan gum, Guar gum, gum arabic, gum tragacanth, and mixtures thereof. Additional gelling agents include polyvinylpyrrolidones. Because the polymers are water swellable, it may be concluded they become more adhesive when wet, encompassing claims 14 and 18. A strip of material is applied to the desired oral surface by the wearer. The side of the material facing the oral surface is coated with a oral care substance that is preferably in a highly viscous state. The strip is held in place for extended periods of time. The strip of material readily conforms to the oral surface by lightly pressing it to the surface. The strip of material is easily removed by peeling it off using a finger or fingernail. Preferably each successive treatment uses a fresh strip of material, which encompasses claim 26 because it implies more than one strip is needed for the completion of treatment. This method encompasses claim 27. The reference differs from the instant claims insofar as it does not teach a protective adhesive composition positioned relative to said barrier layer.

Jensen et al. teach isolation barriers for applying to the gums to protect from irritation caused by teeth whitening gels. The barrier compositions are applied to protect the sulcular as well as the gums against damage caused by the treatment compositions. The applied barrier helps to ensure the treatment composition stays in the desired area to be treated. The barrier also are resistant to deformation at the external surface of the

barrier due to incidental touching and remain adherent to the dental substrate at the internal surface of the barrier (col. 3, lines 1-21). Also included in the barrier composition are tissue adherence accentuators. They include gums, cellulose materials and water-soluble polyethylene oxide polymers, derivatives and equivalents, which encompasses the instant claims referring to a hydrophilic polymer as being apart of the protective adhesive composition. The barriers are applied before the whitening compositions. When applied by syringe, the barrier substantially conforms to the tooth-gum interface. Larger or smaller isolation barriers may be applied depending upon the specific dental procedure (col. 10, lines 33-51). The fact the barriers adhere to the tissue demonstrate they are sticky and viscous, as recited in claim 17. The reference differs from the instant claims insofar as it does not teach applying a strip over the teeth to prevent contact between the tooth whitening compositions and soft tissues of the mouth.

It would have been obvious to one of ordinary skill in the art to have applied a barrier layer to the gums before applying the whitening strip of the primary reference motivated by the desire to protect the sulcular tissue between the arches of the teeth as well as the gums and other oral tissue from damage caused by the whitening composition as disclosed by the secondary reference.

Claims 1-9 and 11-34 are rejected.

Claims 10 and 35-40 are withdrawn.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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